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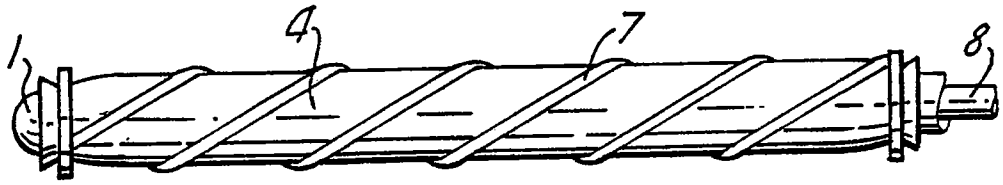
(54) Title: A BALLOON CATHETER AND A METHOD FOR PRODUCING THE SAME



(57) Abstract

A balloon catheter, e.g. for blocking a vein, which comprises a flexible catheter (1), e.g. of polyamide or polyurethane, and a body which may be pumped-up (inflated), which is attached to the end of said cather and consists of a thin rubber hose (4) or the like, which is tightly attached to the catheter at both ends. At the end of said catheter one or a number of openings (3) are provided which communicate with the void of hose (4). When mounted, hose (4) is stretched in its longitudinal direction and twisted about its own axis. In this manner a hose with a large diameter may be packed tightly onto the catheter. A method for producing such a balloon catheter comprises stretching and twisting hose (4) about its own axis before it is attached to catheter (1) at both ends.

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A ballon catheter and a method for producing the same

The present invention relates to a balloon catheter for blocking a vein, which comprises an elastic catheter, e.g. of polyamide, and a body, which can be pumped-up (inflated) and is attached to the catheter end and consists of a thin rubber hose or the like, which is at both ends tightly secured to the catheter, with one or a number of openings provided at the end of the catheter which communicate with the void of the hose. Furthermore, the invention relates to a method for producing such a catheter.

Such a catheter is, e.g. known from US-PS 3 834 394 and was, to some extent, used in praxis.

The object of such a catheter is to insert it in a vein and pump up the inflatable body, preferably, by introducing saline water into the catheter and, thus, inside the inflatable body by the aid of a simple pump mechanism to pump it up. The advantage of using saline water for inflation is that if the balloon catheter should, for some reason, be punctured during pumping operations, the saline water will do no harm by leaking to the blood. Blocking a vein may be of interest, e.g. in case of local treatment of cancer, where the local supply of blood to a tumor or an attacked area is temporarily blocked, at the same time as very concentrated doses of medicaments or cancer drugs can be administered to the rest of the body withouth any danger of harming the rest of the body.. A balloon catheter can, furthermore, be used to dilate constricted veins, anginoplasty. A special area of application is to introduce the catheter, via a readily accessible artery, into aorta and block the latter. In this manner it is possible to stop a life threatening internal haemorrhage which could otherwise only be stopped by a very

hazardious surgical intervention which, per se, would aggravate the condition of the patient, until all sources of haemorrhage are found and are surgically repaired. The advantages of first stopping the haemorrhage by blocking aorta from inside are many. There is time to replace lost blood before the patient is anaesthetized and operated on. This enhances the reserves and possibilities of succeeding if unforeseen obstacles should occur. A far less number of blood transfusions will be needed. In case of injuries it is not uncommon to use 30-50 units of blood at NOK 200,- to 300,- a unit. By closing aorta, conditions are made easily surveyable to the surgeon who can, thus, advance to damaged structures to be repaired or removed. Under common circumstances to day, surgeons have to fight against time and death by bleeding from the moment when the skin is incised and until it is possible to place forceps on aorta or the bleeding vessels. It will be understood that this must be done without guidance of vision, since the area of surgery is filled with blood and is all the time overflowed from injured tissue and bleeding vessels. Under such circumstances it is unavoidable that the surgeon fighting against time may damage or even destroy structures that may be difficult to repair later.

A weakness of the balloon catheters previously tried was that the inflated balloon has a relatively large diameter. This is due to the fact that there is a limit of how much known resilient materials may be stretched. Since aorta has an internal diameter of 3-4 cm, it must be possible to pump up the ballon to a diameter of at least 4-5 cm in order to achieve a safe surface pressure against the walls of aorta ensuring sufficient tightening. With previously known balloon catheters it was, thus, necessary to enter an artery in an inguen or an upper arm to find an artery of sufficiently large diameter so that the previously used balloon catheters could be introduced.

However, for the method of blocking aorta by the aid of a balloon catheter really to be of value, such blocking must be achieved rapidly. Also, so to say any medical practitioner arriving, e.g. at the site of an accident where a person is so severely injured in the lower part of the body that life is endangered, must be able to perform such blocking. Only a few medical practitioners will be able to find an artery in an inguen or upper arm fast enough to save life.

It is, thus, an object of the present invention to disclose a balloon catheter which is sufficiently narrow to permit insertion through a narrow opening, e.g. into a narrow vein, and where it is, nevertheless, possible to inflate the balloon to a sufficient size to block the vein in question in a reliable manner. A special object of the invention is to provide a balloon catheter which is so narrow that it may be introduced in wrist artery (arteria radialis) of the left hand, which will be the obvious choice if aorta is to be blocked by the aid of a balloon catheter. This vein extends up through the arm, over the scapular curve and into aorta on the left hand side of the heart.

The problem, thus, is to provide a balloon catheter with an inflatable body showing a minimum of build-up outside the external circumference of the catheter and yet being strong enough to be inflated to the necessary size in order to bear on the wall of aorta with sufficient force. A special problem is to provide a balloon catheter which is sufficiently narrow to be introduced into arteria radialis, and which has a balloon that is big enough to block the inside of aorta. This means that the catheter, originally, must not exceed a diameter of 3 mm, and it must be possible to inflate the balloon to a diameter generating a contact pressure against the inside of aorta which has a diameter of 10-30 mm. This, viewed in the light of the fact that previously known elastic materials have a physical limit of transversal expansion of 600-800%, i.e. 6-8 times the original width. If

we start from an optimal material with a transversal expansion of 8 times, used in a rubber hose with a diameter of 3 mm, the resulting maximum diameter of the inflated hose will be 24 mm. With such inflation there will be a high risk of punctuation, and even with this diameter it will only be possible to block aorta of very small persons.

According to the invention this is achieved by the aid of a balloon catheter of the above mentioned kind, which is characterized by the fact that the hose is stretched in its longitudinal direction and is twisted about its own axis before it is secured to the catheter at both ends.

It was found that with such stretching the molecules of the rubber organize in the direction of stretching. By stretching the, original diameter of the rubber hose is reduced without its ability of elastic stretching being correspondingly reduced. More force is, indeed, required to inflate the balloon after it was stretched, and it will not tolerate the same physical loads since the wall thickness is reduced due to stretching. By twisting the hose, additionally, in a stretched state, it is possible to pack a hose which originally has a still larger diameter tightly into the catheter and still achieve a very small diameter of the stretched and twisted hose.

By the aid of the invention the ability of the hose of relative transversal expansion may be increased far beyond the 600-800% constituting the physical material determined limit of expansion of the material.

A special embodiment of the balloon catheter according to the invention with a sufficiently small diameter of the balloon material in its starting position and a sufficiently large diameter in an inflated position for reliably to block aorta, is achieved according to the invention by an elastic hose, which is dimensioned to be able to show a diameter of at

least 30-40 mm in a pumped up (inflated) state, which when mounted on the ends of the catheter is stretched in its longitudinal direction to a diameter not exceeding 3 mm.

The tractive forces arising due to the fact that the rubber balloon is mounted in a stretched and twisted state, will cause a common catheter to tend to curve at its end, so that the ends of the rubber hose approach each other. In order to counteract such an undesirable curvature, according to a preferred embodiment of the invention, a resilient string, e.g. a steel sting showing a resilience which is adapted to the tractive forces of the stretched and twisted rubber hose, is inserted into the catheter so that the string and, thus, the outer end of the catheter forms a slight curve, not exceeding 30^{o}.

According to a further development of the invention the catheter is a two or three-passage catheter. In this manner pressure may be measured and/or an X-ray contrast medium may be injected on either side of the balloon.

A method according to the invention for the manufacture of a catheter of the above mentioned kind is characterized by the fact that the hose is stretched and twisted about its own axis before it is secured to the catheter at both ends.

A special advantage is achieved by relieving part of the stretching after twisting the hose.

The invention is disclosed in more detail below with reference to the drawing, where

Figure 1 shows a sectional view through the outer end of a catheter according to the invention during application of the rubber hose,

Figure 2 shows the end of the balloon catheter with the hose fully stretched and twisted,

Figure 3 on a smaller scale, shows how the outside end

of the catheter is bent due to tractive forces,

Figure 4 shows how the catheter is straightened by the aid of the string, and

Figure 5 shows the introduction path of a catheter according to the invention.

The balloon catheter comprises a flexible catheter 1, e.g. of a polyamide, and with a diameter between 2 mm and 3 mm. The catheter is closed at end 2, and has a number of openings 3 close to said end. At the end, a very thin rubber hose 4 is mounted by being clamped onto the circumference of the catheter by clamping rings 5 and 6. The rubber hose must be attached so as to prevent any leakage between rubber hose and catheter. The equipment, furthermore, comprises a string 8 which can be inserted in the catheter passage. Other manners of attaching rubber hose 4 apart from by the shown clamping rings will readily be found. The attachment may be provided, e.g. by welding or glueing.

Rubber hose 4 has a diameter of approximately 5 mm, but when mounted, it is stretched to bear tightly on the outside of the catheter and, thus, only increase the diameter of the device by a minimum.

Figure 2 shows how rubber hose 4 is attached on catheter 1 in a stretched and twisted state. Slight folds 7 are formed, but in spite of its large original diameter the hose will bear tightly on the catheter 1.

It will appear from Figure 3 how tractive forces in the stretched rubber hose bend the catheter in spite of the stiffening effect of spring 8. Without the spring the catheter would be bent to an U-shape.

Figure 4 shows how the outer end of the catheter is straightened by insertion of string 8 into a passage of the catheter.

Figure 5 is a diagrammatical illustration of how the catheter is inserted to close aorta. A small incision 9 is made in the patient's left wrist 10 to open the artery in the wrist (arteria radialis). Catheter 1 is inserted into the artery and is moved up through the arm and over the shoulder curve, and into curved aorta 11 above the heart 12. During this step of the introduction, string 8 is conveyed all the way forward to end 6 of the catheter to keep the latter staight at its end. The catheter is advanced until end 6 bears against the wall of the artery, and is then retracted a number of centimeters, until the end of the catheter sits at upper portion of aorta. Then the string is slightly retracted, so that the end of the catheter flexes as shown in the full line representation. Then the catheter is advanced further down along aorta 13, e.g. down to the area of the midriff 14. In this position the rubber hose or balloon 4 is inflated by pumping in saline water at the outer end of catheter 1. This may be executed by the aid of a common syringe.

In the embodiment catheter 1 is shown in the shape of a one-passage catheter. The catheter may, however, have two or three passages, permitting pressure measuring and/or introduction of an X-ray contrast medium on either side of the ballon by the aid of the additional passages. The balloon is slowly filled with saline water until the pressure distally of (below) the balloon falls below 10 mm Hg. When a one-passage catheter is used, the pressure may be measured by sensing the inguinal pulse and/or the blood pressure may be measured on the other arm.

The balloon is deflated as soon as a surgical survey has been gained and the sources of bleeding are under control.

Due to the fact that the device according to the invention can be introduced in the wrist artery, the entire procedure

may be carried out in 2-5 minutes and it may be carried out be the youngest assisting doctor.

By the aid of the catheter according to the invention blood supply to any injured area below the midriff may be blocked, and this may be compared to turning off the main cock of a house where there is a large leakage of the pipeline inside the house. The surgeon is, thus, able to work without being pressed for time and can see what he is doing. At the same time as blood supply is cut off to the lower part of the body, sufficient pressure is created in the remaining parts of the body to maintain circulation, which is necessary for life to go on. Improved working conditions for the surgeon permit the operation to be more controlled by the aid of eyesight, which will reduce the hazard of inflicting unintended injuries.

Due to the pressure generating effect, the invention is not only effective in cases of severe bleeding, but also in cases of cardiac arrest. It may also be of importance with transplantations, especially by increasing and improving access to organs, which is to day the most important limitation of transplantation of organs.

PATENT CLAIMS:

1.
A balloon catheter for blocking a vein, which comprises a flexible catheter (1), e.g. made of polyamide, and a pumpable (inflatable) body, which is attached to the end of the catheter and consists of a thin rubber hose or the like which is at both ends tightly secured to the catheter, and where, at the end of the catheter one or several openings (3) are provided which communicate with the void of hose (4), c h a r a c t e r i z e d i n that in mounting said hose (4) is stretched in its longitudinal direction and twisted about its own axis.

2.
A balloon catheter according to claim 1, c h a r a c t e r i z e d i n that said hose is dimensioned to be able to assume a diameter of at least 30-40 mm in a pumped up (inflated) state, and that the hose, when mounted at the end of catheter (1), is stretched in its longitudinal direction to have an external diameter not exceeding approximately 3 mm.

3.
A balloon catheter according to claim 1, c h a r a c t e r i z e d in that a resilient string (8), e.g. a steel string having a resilience which is adapted to the tractive force of the stretched and twisted rubber hose (4) is inserted into catheter (1), so that the string and, thus, the end of catheter (1) forms an open curve, not exceeding 30^{o}.

4.
A balloon catheter according to claim 1 or 2, c h a r a c t e r i z e d i n that catheter (1) is a one, two or three-passage catheter.

5.
A method for producing a balloon catheter for blocking a vein, which comprises a flexible catheter (1), e.g. made from polyamide, and a body which may be pumped up (inflated) and consists of a thin rubber hose or the like, which is at both ends tightly attached to said catheter, and where one or a number of openings (3) are provided at the end of the catheter which communicate with the void of hose (4), c h a r a c t e r i z e d i n that hose (4) is stretched and twisted about its own axis before it is attached to catheter (1) at both ends.

6.
A method according to claim 5,
c h a r a c t e r i z e d i n that part of the stretching is relieved after twisting has been carried out.

7.
A method according to claim 5,
c h a r a c t e r i z e d i n that the catheter is manufactured from a material having a resiliency which is adapted to the tractive force of the stretched rubber hose (4), so that the outside end of the catheter forms an open curve, not exceeding 30^{o}.

Fig.1.

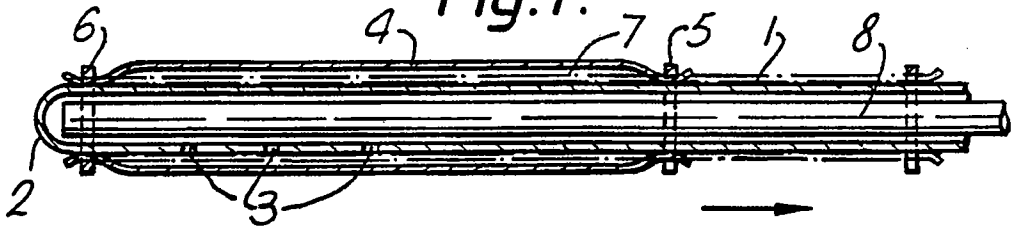


Fig.2.

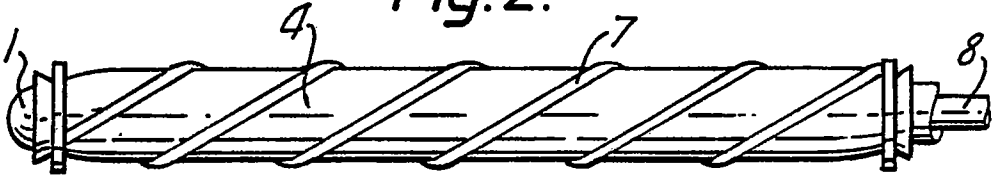


Fig.3.

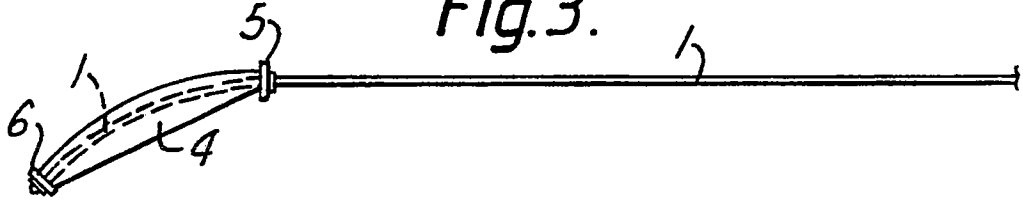


Fig.4.

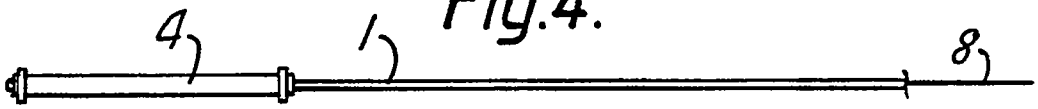
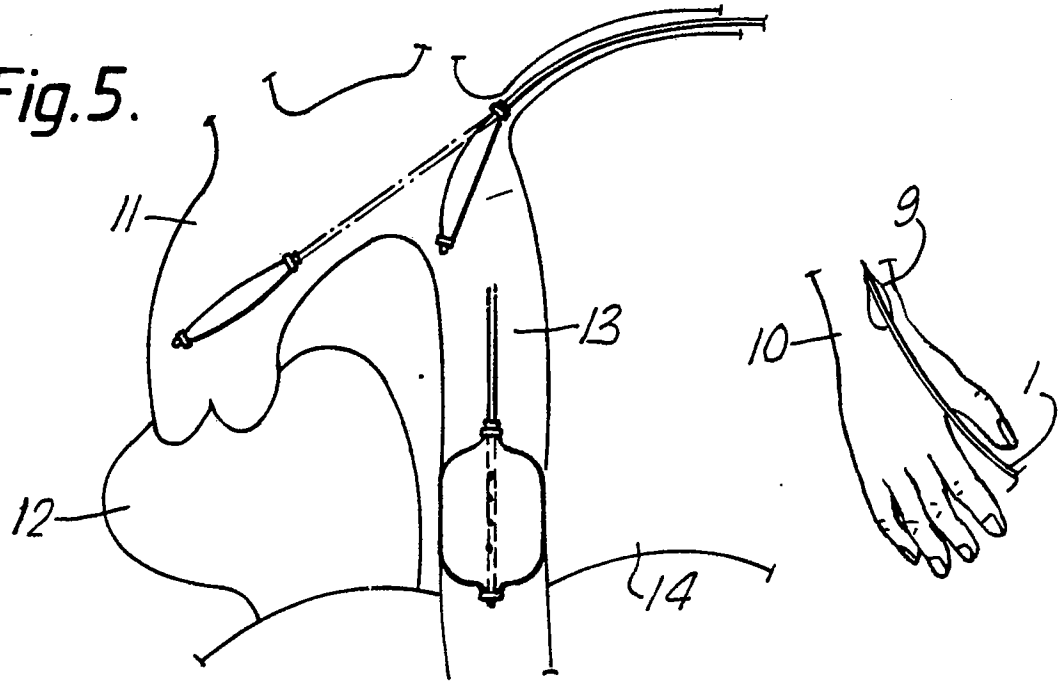


Fig.5.



INTERNATIONAL SEARCH REPORT

International Application No PCT/NO89/00052

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *

According to International Patent Classification (IPC) or to both National Classification and IPC 4

A 61 M 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched 7

Classification System	Classification Symbols
IPC 4	A 61 M 23/00, 25/00-02, 29/00-02
US Cl	128:303.11, 344, 348-350; 604:19, 27, 36, 37, 48, 51-54, 93, 96-104, 244, 257, 263, 264, 275, 276, 280, 282, 283

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched 8

SE, NO, DK, FI classes as above

III. DOCUMENTS CONSIDERED TO BE RELEVANT 9

Category *	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13
A	US, A, 4 655 748 (MUSHIKA) 7 April 1987	1-7
A	US, A, 4 338 942 (FOGARTY) 13 July 1982	1-7
A	US, A, 4 292 974 (FOGARTY ET AL) 6 October 1981	1-7
A	FR, A1, 2 455 465 (DATASCOPE CORP.) 28 November 1980	1-7
A	EP, A1, 0 047 465 (KONTRON CARDIOVASCULAR INC.) 17 March 1982	1-7

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IV. CERTIFICATION

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